UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/875,456	06/06/2001	Ning Qin	ORT 1448	6286

27777 7590 04/01/2003

AUDLEY A. CIAMPORCERO JR.
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER
ULM, JOHN D

ART UNIT	PAPER NUMBER
1646	12

DATE MAILED: 04/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/875,456	Applicant(s) Qin
	Examiner John Ulm	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Dec 23, 2002 .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-34 is/are pending in the application.

4a) Of the above, claim(s) 14-16 and 18-34 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-13 and 17 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7, 8, 9
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1) Claims 1 to 34 are pending in the instant application.

2) Claims 14 to 16 and 18 to 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 11, filed 23 December of 2002. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3) Claims 5 and 9 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Each of these claims appears to be drawn to alternative embodiments of the claims from which they depend. A properly dependant claim can not conceivably be infringed without infringing any of the claims from which it depends. See M.P.E.P. 608.01(n)III..

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4) Claims 1 to 3, 5 to 7, 9 to 13 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected,

to make and/or use the invention. These claims require an isolated polynucleotide encoding a "Human β1A sodium channel subunit" having other than the amino acid sequence presented in SEQ ID NO:14 of the instant application. No other "Human β1A sodium channel subunit" is disclosed or suggested by the instant specification. Whereas the instant claims encompass an isolated polynucleotide encoding any protein which might be encompassed by the term "Human β1A sodium channel subunit", the only "Human β1A sodium channel subunit" that is described in the instant specification in sufficient detail to permit and artisan to make and use an isolated polynucleotide encoding it is the "Human β1A sodium channel subunit" comprising the amino acid sequence presented in SEQ ID NO:14 of the instant application. Because the alteration of 10% of the nucleotide bases in the protein coding sequence of a polynucleotide can result it the alteration of as much as 30% of the amino acid residues encoded thereby, claim 1 encompasses a polynucleotide encoding a "Human β1A sodium channel subunit" whose amino acid sequence can deviate from SEQ ID NO:14 by as many as 201 out of the 268 amino acid residues in that sequence. The instant specification, however, does not describe even one working example of a "Human β1A sodium channel subunit" having other than that single, naturally occurring amino acid sequence presented therein. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that:

> "Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by

claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

Because the instant specification does not identify those amino acid residues in SEQ ID NO:14 which are critical to the structural and functional integrity of a "Human β1A sodium channel subunit" comprising that sequence, identify a structurally analogous protein for which this information is known and could be applied to the instant protein by extrapolation, or even provide a single working example of an intentionally modified protein of the instant invention, an artisan can not change even a single residue within the amino acid sequence of SEQ ID NO:14 and predict the effects of that change on the performance of that protein "by resort to known scientific law". In the absence of this information a practitioner would have to resort to a substantial amount of undue experimentation in the form of insertional, deletional and substitutional mutation analysis of over 268 amino acid residues before they could even begin to rationally design a functional "Human β1A sodium channel subunit" having other than a natural amino acid sequence. The disclosure of a single DNA sequence encoding a single "Human β1A sodium channel subunit" with a natural amino acid sequence is clearly insufficient support under the first

paragraph of 35 U.S.C. § 112 for claims which encompass any and all "Human β1A sodium channel subunits", including mutants and variants thereof, which are encoded by a DNA which hybridizes to a DNA having that single disclosed sequence under "stringent hybridization conditions" as recited in claim 17.

The current claim limitations are directly analogous to those of claim 7 of U.S. Patent Number 4,703,008 which were held to be invalid under 35 U.S.C. § 112, first paragraph, for want of enablement in *Amgen Inc. v. Chugai Pharmaceuticals Co. Ltd.*, 18 U.S.P.Q. 2d, 1016 (CAFC, 3/5/91, see page 1026, section D). In that instance, a claim to a nucleic acid encoding a polypeptide having an amino acid sequence sufficiently duplicative of the amino acid sequence of erythropoietin (EPO) so as to have a specified biological activity was held to be invalid under 35 U.S.C. § 112, first paragraph, for want of enablement. This limitation is directly analogous to the hybridization limitation of instant claims 14 and 17 and narrower than the limitations of claims 7, 10, 11 and 13, which recite no structural limitations at all. The disclosure upon which that claim was based described a recombinant DNA encoding EPO and a few analogs thereof. That disclosure differs from the instant specification because, whereas the instant specification describes a single cDNA encoding a "Human β1A sodium channel subunit", it does not describe even a single mutant or variant thereof. The court held that what is necessary to support claims of this breadth is a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of the claims. For DNA sequences, that means disclosing how to make and use enough sequences to justify the grant of the claims sought. As indicated, the instant

specification is even more limited than the '008 patent because it describes only a single protein and no analogs or mutants thereof and, therefore, provides even less support than the '008 specification for claims of comparable scope and which were held to be invalid in that patent.

5) Claims 1 to 3, 5 to 7, 9 to 13 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims essentially encompass any isolated polynucleotide encoding any protein which is encompassed by the term "Human β1A sodium channel subunit". The instant specification, however, does not describe the genus of polynucleotides claimed or the genus of proteins encoded thereby. Whereas the genus of polynucleotides encompassed by these claims is potentially very large, the instant specification only describes one species within the claimed genus. In the decision of *The Regents of the University of California v. Eli Lilly and Company,* 43 USPQ2d 1398 (CAFC 1997), the court held that:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious,"

and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Whereas the instant specification provides a detailed description of a single isolated DNA encoding a particular "Human β1A sodium channel subunit" having very specific physical and structural properties, the instant specification does not provide a chemical or structural formula which is definitive of all "Human β1A sodium channel subunits". Because the instant specification does not identify those features which distinguish "Human β1A sodium channel subunits" as a group from β1A sodium channel subunits which originate in chimpanzees, orangutans or other primates, and because it fails to describe a representative number of species of polynucleotide within the claimed genus, the instant specification does not support the breadth of the instant claims.

6) Claims 5, 6, 8 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

was filed, had possession of the claimed invention. These claims expressly require a genomic DNA encoding a "Human β1A sodium channel subunit" or a polynucleotide encoding an . However, the instant specification does not provide an adequate written description of a genomic DNA encoding a "Human β1A sodium channel subunit" or any other genomic DNA. Because the instant specification does not identify those structural and/or chemical features which distinguish a genomic DNA encoding a "Human β1A sodium channel subunit" from any other DNA encoding this protein it fails to demonstrate that Applicant was in possession of the claimed species of DNA at the time that the instant application was filed. Further, claim 1 expressly encompasses an isolated polynucleotide which encodes a "Human β1A sodium channel subunit" and which is complementary to a polynucleotide that encodes a "Human β1A sodium channel subunit". There is absolutely no description in the specification of an isolated polynucleotide which encodes a "Human β1A sodium channel subunit" in both a sense and antisense direction.

7) Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This claim encompasses a process for expressing a "Human β1A sodium channel subunit" in a recombinant host cell, however, the claim does not require the presence of a nucleic acid encoding a "Human β1A sodium channel subunit" in the cell being employed in the claimed method. The vast majority of nucleic acid vectors which could meet all of the material limitations recited in section (a) of this claim would not be expected to encode a "Human β1A sodium

channel subunit", and the instant specification does not provide the guidance that would be needed by a practitioner of the art of molecular biology to produce a "Human β1A sodium channel subunit" in a cell that does not contain a nucleic acid encoding a "Human β1A sodium channel subunit".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8) Claims 1 to 13 and 17 are vague and indefinite in so far as they employ the term "Human β1A sodium channel subunit" as a limitation. Because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a "Human β1A sodium channel subunit" an artisan can not determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.

8.1) Claims 5, 7 and 9 to 13 are vague and indefinite because the metes and bounds of the limitations "allelic variants", "mutants" and "functional derivatives" are undeterminable. For example, an "allelic variant" or mutant" of a gene can include the complete absence of a gene product. Further, it is unclear how a "functional derivative" of a "Human β1A sodium channel subunit" differs from a "Human β1A sodium channel subunit".

8.2) Claims 4, 5, 8 and 12 are confusing because it is unclear if the sequence identifiers contained within the parenthesis are exemplary or limiting. This is particularly true for claim 5, which is grammatically incorrect.

8.3) Claim 6 is vague and indefinite because there is no antecedent basis for "said DNA molecule".

8.4) Claim 17 is vague and indefinite because the limitation "stringent hybridization conditions" is conditional and no single set of defining conditions is recited in the claim or the specification. The specific hybridization conditions described on page 26 of the instant specification are expressly identified therein as exemplary.

9) The prior art of record did not disclose or suggest an isolated polynucleotide encoding the amino acid sequence presented in SEQ ID NO:14 of the instant application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN ULM
PRIMARY EXAMINER
GROUP 1600